

Notice of Allowability

Application No.

10/038,722

Examiner

William W. Moore

Applicant(s)

LEY ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Terminal Disclaimer and Amendment filed 21 March, and the interview of 7 April, 2005.
2. ☒ The allowed claim(s) is/are 43-52.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 6/21/02
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413),
Paper No./Mail Date 13 June 2005.
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

22

ALLOWANCE

Information Disclosure Statements

Applicant's Information Disclosure Statement [IDS] filed 8 January 2002 indicated where the disclosures of one parent application, serial No. 08/133,031, were incorporated into the disclosure of a more recent parent application, serial No. 08/849,406 but cited no US Patents or Pre-Grant Publications, no foreign patents, and no non-patent literature. No PTO-Form 1449 accompanied the IDS filed 8 January 2002. Thus this IDS is not indicated as an attachment in Item 3 of the Notice of Allowability. Since both cited parent applications were abandoned, they are not cited as US Patents on the accompanying PTO-Form 892. A PTO-Form 1449 accompanied the second IDS filed 21 June 2002, citing non-patent literature, was executed, is cited as an attachment in Item 3 of the Notice of Allowability, and accompanies this communication.

Preliminary Amendments and Terminal Disclaimer

Claims 1-42 were cancelled and claims 43-52 added in Preliminary Amendments filed 18 January and 18 April 2005. Preliminary Amendments to the Specification filed 7 June 2002 and 21 March and 18 April 2005 were entered, clarifying the disclosure, setting forth Applicant's claim to priority, providing Sequence Identifiers for sequences that appear the text of tables in the Specification and also providing amended computer-readable and printed forms of the Sequence Listing to bring the specification into compliance with 37 CFR 1.182. The Preliminary Amendments filed on 7 June 2002 and on 21 March and 18 April 2005 introduce no new matter to the specification. Applicant's Terminal Disclaimer filed 21 March 2005 has been reviewed and is ACCEPTED.

Priority

The instant application is granted the benefit of priority to serial No. 08/358,160 filed 16 December 1994, wherein modified second Kunitz domains of the human Inter- α -

Art Unit: 1652

Trypsin-Inhibitor of claims 43-48 were first disclosed, which is the effective filing date for the subject matters claimed herein.

Restriction/Election

Applicant's election without traverse in the reply filed on 18 January 2005 of the invention of Group I, wherein the species of variant Kunitz domain inhibitor having the amino acid sequence set forth in SEQ ID NO:27 was also elected without traverse, is acknowledged. A search conducted pursuant to Applicant's election of SEQ ID NO:27 also reached other disclosed variant Kunitz domain inhibitor sequences, e.g., SEQ ID NO:26, based on the second Kunitz domain of the human Inter- α -Trypsin-Inhibitor (ITI-D2). The restriction requirement of record as to species is therefore WITHDRAWN with regard to the variant Kunitz domain inhibitor species of claims 43-48, and these species were examined. Further in view of the election of species, the restriction requirement of record as between methods of Groups II and III is also WITHDRAWN insofar as the new claims 49-52 require the elected and examined Kunitz domain inhibitor species.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

The claimed subject matter is free of the prior art of record herein. Although Nakano et al., US 5,541,288, disclose, see claim 1, a substitution of phenylalanine for the isoleucine at position 18 of SEQ ID NO:25, their disclosure is available only as of 16 December 1994, thus cannot provide a description in a "patent granted on . . . an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent". Fritz et al., US 4,407,915, made of record herewith, disclose an amino acid substitution of isoleucine for the arginine present at position 15 of SEQ ID NO:25, but teach away from further amino acid substitutions at positions 3 and 18-20 of SEQ ID

Art Unit: 1652

NO:25 by teaching instead amino acid substitutions at positions 17 and 30 in the human ITI-D2 Kunitz domain. Nii et al., also made of record herewith, disclose an amino acid substitution of phenylalanine for the isoleucine at position 18 of SEQ ID NO:25 herein, see Table 1 at page 1110, but teach away from further amino acid substitutions at positions 3, 15, 19 and 20 of SEQ ID NO:25 by choosing substitutions at position 19 of SEQ ID NO:25 other than proline, by choosing to make no substitutions at positions 3, 15, and 20 of SEQ ID NO:25, and by choosing instead to combine the substitutions Q19K and Q19R with further substitutions at position 46 of SEQ ID NO:25. Thus the prior art of record does not disclose or fairly suggest combining amino acid substitutions at positions 15 and 18 of SEQ ID NO:25 of, respectively isoleucine and phenylalanine, or any amino acid substitutions at positions 3, 19 and 20 of SEQ ID NO:25 required by claims 43-48 herein. Claims 43-52 are allowed herewith.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion


Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William W. Moore whose telephone number is now 571.272.0933. The examiner can normally be reached between 9:00AM and 5:30PM EST. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can now be reached at 571.272.0928. The

Art Unit: 1652

fax phone number for all communications for the organization where this application or proceeding is assigned is 571.273.8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is now 571.272.1600.

William W. Moore
13 June 2005


NASHAAT T. NASHED PHD.
PRIMARY EXAMINER